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March 6, 2013
2:00 p.m. EST
Call Duration: 20 minutes

JODY ENGEL: Good afternoon and welcome. Thank you very much for joining this telebriefing to discuss the findings of the NIH Consensus Development Conference on Diagnosing Gestational Diabetes Mellitus. The conference was held at the National Institutes of Health in Bethesda, Maryland, March 4th through 5th, 2013, and was co-sponsored by the NIH Office of Disease Prevention and the *Eunice Kennedy Shriver* National Institute of Child Health & Human Development.

For those of you who not familiar with the NIH Consensus Development Conferences, there are a few points to bear in mind. The members of the consensus panel were selected in part because they have expertise in relevant fields, including obstetrics and gynecology; maternal-fetal medicine; biostatistics; clinical research in the areas of diabetes, neonatal and perinatal medicine, and pediatrics; women's health issues; health services research; decision analysis; health management and policy; health economics; epidemiology; and community engagement.

The panel members were also viewed by their peers as highly skilled in critically examining scientific evidence. Biographies of the panel members are available on the GDM conference website. Go to prevention.nih.gov/gdm and click on "media resources".

The panel members have spent the last several weeks reviewing published literature, and have spent the last two days absorbing testimony from experts in the field and the conference audience. Following the conference presentations and discussions, the panel met in executive sessions to weigh the evidence and prepare their statement, which answers seven key conference questions.

The panel members performed this task on a volunteer basis. The NIH covers their expenses for traveling to the conference, but they are not compensated for their time. It is also important to recognize that the panel issues its statement as an independent group. Their statement does not represent a policy or position statement of the National Institutes of Health or the Federal Government.

The panel's draft statement, marked March 5th, 2:24 p.m. Eastern Standard Time is now posted on the conference website and is available at prevention.nih.gov/gdm. The final statement will be available in approximately six weeks.

I have a few procedural points to cover before turning things over to our panel chair, Dr. Peter VanDorsten. Dr. VanDorsten will provide a brief overview of the panel's findings, after which there will be time for questions, which will be answered by Dr. VanDorsten.

The telebriefing will end promptly at 3:00 p.m., if not before. Press star, 1 on your telephone keypad to be placed in queue to ask a question. A moderator will recognize you in turn and will unmute the line so you can speak. And finally, only members of the media are permitted to ask questions during this telebriefing. Other interested parties are welcome to listen in, but will not be recognized to address the panel with questions. There will be a playback of this telebriefing available shortly after the call. Just dial 1-888-632-8973 and enter the replay code 38277108. This information is also posted on our media resources page.

With that, I'll turn things over to our panel Chair, Dr. Peter VanDorsten, of the Medical University of South Carolina. Dr. VanDorsten?

DR. PETER VANDORSTEN, MEDICAL UNIVERSITY OF SOUTH CAROLINA: Yes, thank you, Jody. First, let me say it was a real pleasure for all 15 of us on the panel to participate in the Consensus Conference on Diagnosing Gestational Diabetes Mellitus or GDM as we refer to it.

We reviewed the current scientific data and provided recommendations in our draft statement. As you know, the panel recommended following the current diagnostic approach until further studies are conducted. Before taking questions, let me review our deliberations.

GDM is a condition in which women without previously diagnosed diabetes exhibit high blood glucose levels during pregnancy. GDM is currently estimated to occur in 5 to 6 percent of U.S. pregnancies, affecting more than 240,000 births annually. GDM is associated with an increased risk of complications for both the mother and the child, including maternal high blood pressure, cesarean delivery, and neonatal low blood sugar.

Additionally, up to one-half of women who have experienced GDM during pregnancy will develop type 2 diabetes later in life. Different approaches are used to identify GDM and the number of women diagnosed varies with the test criteria that are used. Tests differ based on whether there's a need for fasting, the grams of glucose given, the number of appointments, and the glucose thresholds for diagnosis.

Most health care providers in the United States use a two-step approach that involves a non-fasting glucose screening of all pregnant women, followed by a glucose tolerance test for a subset of these. However, many other countries and prominent organizations such as the American Diabetes Association now support a one-step approach for all pregnant women.

There is much debate regarding the choice of tests and the tradeoffs of each approach. After reviewing the evidence, the panel found certain operational advantages to the one-step approach, including a consistent diagnostic standard across one's lifespan and better comparability of research outcomes globally.

From a clinical perspective, the one-step approach can promote better standardization of patient care and allow a diagnosis to be achieved within the context of one clinic visit as opposed to two. However, despite potential benefits, there are several concerns about the one-step approach.

This approach is anticipated to increase the frequency of the diagnosis of gestational diabetes by two to three fold to a prevalence of approximately 15 to 20 percent as opposed to the current 5 or 6 percent. There's evidence that the labeling of these women may have unintended consequences, such as an increase in life disruptions, anxiety, clinic visits, cesarean delivery, and more intensive antenatal and newborn assessments.

Moreover, the care of these women will generate additional direct and indirect health care costs. We believe that additional research should be conducted to resolve key research gaps. An initial step would be to assess cohorts that are using the single-test approach currently, to determine if more stringent diagnostic criteria would identify a population similar in prevalence and risk to that currently identified by the two-step approach now in use in the U.S.

Subsequent research that focuses on women with less severe disease could help to determine if they would summarily benefit from this diagnostic approach. We determined that health services research should be performed to see if less expensive but equally or more effective approaches can be found for the management of GDM.

We recommended that prospective cohort studies be conducted of the real world impact of GDM treatment on care utilization. We also support additional research to understand patient preferences and the psychological consequences of a diagnosis, given that different approaches represent different burdens for patients.

Finally, we concluded that interventions during pregnancy can lead to long-term improvements in the health care of women, children and families. Healthy lifestyle interventions for women diagnosed with GDM, such as physical exercise and medical nutrition therapy may be of value, and opportunities to assist these women in making healthy changes should not be missed.

Now, I'd be happy to answer any specific questions.

JODY ENGEL: Thank you very much, Dr. VanDorsten. I think we are ready to take the first question.

OPERATOR: As a reminder, ladies and gentlemen, if you do have a question, please press star, 1 on your telephone keypad at this time. As we wait to see if there are any additional questions, I'd like to point out there will be a playback of this telebriefing available shortly after the call. Just dial 888-632-8973. The replay code is 38277108.

And our first question is from Lauren Neergaard from the Associated Press. Please state your question.

LAUREN NEERGAARD, ASSOCIATED PRESS: Hi, thanks, it's Lauren Neergaard with AP. Could you give a little information on where we might start these cohort studies? How many groups in the U.S. have made this switch to the one-step testing approach? And how many other places around the world are doing it? Is it pretty much standard in places like Canada and Britain and Australia as well?

DR. PETER VANDORSTEN: It's a great question. The impetus for the change came from an international multicenter study of 15 different centers worldwide, where they showed that increasing glycemic levels during pregnancy associated with various maternal, fetal and neonatal morbidities.

Based on those data, a consensus panel from the International Association of Diabetes and Pregnancy Study Groups met on two different occasions to come up with these suggestions. The American Diabetes Association embraced the concept and there are a number of institutions, not surprisingly, many of them are institutions that participated in this study. But there are places in the United States that have started doing it.

We heard during the course of deliberations, for instance, that they're doing it at Northwestern. We're aware that there are places in California where it's being done. Obviously, there are many places worldwide that are doing it, but there has been limited follow-up information about the impact that it's had.

Clearly U.S. institutions that are dealing with a prevalence of 5 to 6 percent that are now going to be confronted with 15 to 20 percent, or perhaps more in terms of prevalence, are going to have a pretty steep learning curve. But we need information from the so-called real world as to the impact this is having on patients, on obstetrical and fetal and neonatal outcomes before subjecting many more women to the impact of a diagnosis of gestational diabetes.

LAUREN NEERGAARD: And for the second part of my question, do we have that kind of data from places like Canada or Australia or Britain?

DR. PETER VANDORSTEN: We don't and that's what the consensus panel felt that was absent, because in the meantime, we do have data that shows that the way we're doing it now, with a two-step approach, the pregnant woman undergoes a glucose challenge test. It's a 50 gram one-time test, it can be given any time during the day. And the 15 to 20 percent that fail that test then go on to a three-hour glucose tolerance test of four blood sugar fasting one, two- and three-hour test.

We have evidence that those who are diagnosed as having gestational diabetes during the current system, who undergo treatment, and that treatment includes nutritional counseling, sometimes insulin, often more clinic visits, there's evidence that impacts outcome about which we are concerned. We don't have the evidence that enhancing the population provides a benefit for that additional group.

So until we get that information, we felt it premature to exact these increased challenges to the health care system, the health care providers, and more importantly the patients themselves.

LAUREN NEERGAARD: If I could follow up, I guess what I don't understand here is do we not have that data because other places that have adopted this have adopted it so recently?

DR. PETER VANDORSTEN: Exactly. These guidelines are only a year or so old. So we just haven't had a chance to get the robust information that we would need in order to move to the next step. The panel understands that operationally, it makes sense to get in line with what's being done in the rest of the world, where a 75 gram one-time challenge is given to all pregnant patients, because that's the same test, frankly, that we use in the United States in the non-pregnant population.

So we understand that practicality operationally. But we don't feel like there is robust enough data now to subject more patients until we have evidence that there are improved incomes, until we have evidence that the benefits of extending the diagnosis outweigh the potential harms. So we absolutely left the door ajar for reconsideration, should these data be forthcoming.

LAUREN NEERGAARD: Thank you.

DR. PETER VANDORSTEN: You're welcome.

OPERATOR: And our next question is from Tara Haelle, from IMNG Media. Please state your question.

TARA HAELLE, IMNG MEDIA: Hi, yes. I guess my question is actually kind of a follow up to the question from AP, which was what kind of timetable we're looking at before we can have this research to revisit the issue of whether or not we should look at the single step?

DR. PETER VANDORSTEN: The advantage in the NIH getting involved in these kinds of issues, where there are disparate recommendations, is that often the funding agencies follow suit. In other words, if the NIH in its deliberations shows that there are gaps in scientific data, often the money follows. In other words, there's support for research agendas which would look at these questions.

Because, clearly, everybody wants to know, if we can extend benefits to mothers, their unborn children and ultimately their children and impact their future health care, everyone would want to

get on board. Even if it were more expensive, as long as the benefits outweigh the potential harm.

As you know, just the label of diabetes changes one's life: obviously, during the pregnancy in terms of more clinic visits, more diabetic screening, ultimately insulin, more testing, potentially a higher cesarean delivery rate. I mean everybody understands these kinds of requirements, but if they're beneficial to unborn children, to children later and to mothers, I think most people would agree that it's something that we would want to do.

Until then, that label of gestational diabetes to take more patients is going to be problematic.

TARA HAELLE, IMNG MEDIA: Thank you.

DR. PETER VANDORSTEN: You're welcome.

OPERATOR: Thank you. If someone else would like to ask a question, please press star, 1 on your keypad.

DR. PETER VANDORSTEN: Are there more questions?

OPERATOR: Again, ladies and gentlemen, if you would like to ask a question, please press star, 1 on your keypad. At this point, we have no other questions.

JODY ENGEL: OK, well, thank you. I would like to thank our hard-working panel chair, Dr. VanDorsten as well as the reporters that are on the line, and those that will be listening to the replay, we hope you'll join us for future telebriefings. So again, thank you and have a great afternoon.

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